

## REMARKS

Applicant's counsel thanks the Examiner for the careful consideration given the application and for the courteous telephone interview conducted on October 6, 2009 between applicant's counsel and S.P.E. Michael Woodward and Examiner Aradhana Sasan. The substance of the telephone interview is as follows.

Applicant's counsel first summarized the problem to be solved by the invention. It has been known for a long time that it is difficult to get the physiologically active substances, such as choline chloride, into the abomasum of a ruminant, where it can be absorbed. The problem is that the physiologically active substance will first remain in the rumen of the ruminant for an extended period of time, where it is hot and moist. Choline chloride and many physiologically active substances are very deliquescent or hygroscopic and thus quickly absorb moisture in the rumen and dissolve and are degraded so they are not available in the abomasum. What is needed is a "rumen bypass" particle, that is, a particle which passes through the rumen without being decomposed or degraded and thereafter arrives in the abomasum, where it can be dissolved and absorbed so that the physiologically active substance can be effectively utilized by the ruminant. It has been known for a long time to coat the particle of physiologically active substance with a lipid, such as vegetable oil, to protect the substance from decomposition/degradation in the rumen; this is known as rumen bypass and an example of this technology is US 4,948,589.

Applicant's counsel also explained during the interview the critical innovation of the present invention. The present inventors discovered that, when you take a traditional rumen by-pass particle (having a core with the physiologically active substance and a first coating layer of a hydrophobic lipid, such as vegetable oil) and pelletize the particles in a pelletizer, the first layer would be cracked or abraded or rubbed off or otherwise damaged or compromised so that it could not effectively do its job of protecting the core (hygroscopic material) from attack by the humidity in the rumen. The present inventors discovered that the solution to this problem was to apply a second layer of carnauba wax over the first layer. The second layer of carnauba wax was hard enough and tough enough to protect the first layer from degradation during the pelletization process. They discovered that it was critical to the success of the invention to have two layers, each layer of a particular material; the first layer was a hydrophobic substance selected from the group consisting of vegetable oils, hydrogenated vegetable oils, stearic acid

and mixtures thereof; the first layer is to serve the traditional purpose of rumen by-pass, that is, to protect the hygroscopic core material from humidity attack in the rumen; the second layer, mainly consisting of carnauba wax, was needed to effectively protect the first layer and the core from degradation from abrasion, pressure, and mechanical and thermal stress encountered during the pelletization of the particles into an animal feed pellet.

During the interview, applicant's counsel also described the applied references. First, Iijima, et al. (US 4,948,589) was discussed; this teaches the original rumen by-pass technology, that is, a core of physiologically active substance which is hygroscopic, coated with a first layer of a lipid, such as vegetable oil or wax; all of this is discussed at column 1 lines 7-47 and column 3 lines 34-40 and 50-56. However, this reference does not say anything about adding any additional layers, such as a second layer to protect during pelletization. Examiner Woodward did point out that, in '589, at column 8 lines 32-55, it could be construed that the tallow in line 37 was the first layer and that the tallow in line 50 was the second layer. Applicant's counsel explained that the tallow in line 37 was simply the binder to hold the choline chloride together in the core. To overcome this interpretation, applicant's counsel agreed to add the limitation "said core comprising choline chloride and binder" to claim 1. This now makes clear that the tallow in line 37 is binder for the core and that the tallow in line 50 would be the first layer.

The next reference discussed was Spires (US 4,394,377). This reference simply teaches the fact that dietary choline for animals can be combined with antibiotics and pelletized for animal feed purposes. However, this reference does not add any coating layers prior to pelletization. The next reference discussed was Ito et al. (US 6,299,912). This reference is not directly on point, since the core material, L-ascorbic acid-2-phosphoric ester salt, has very low solubility in water, and thus is not a hygroscopic material particularly susceptible to humidity attack in the rumen. Nonetheless, it does teach to coat the ester salt with a digestible and non-hydrophilic coating, such as vegetable oil or wax (column 5 lines 1-17), much like the traditional rumen by-pass layer discussed above. In this regard, '912 is like all the other conventional or traditional rumen by-pass patents which teach a single layer of hydrophobic substance coating to protect the core from humidity attack in the rumen. '912 does mention, among many other processes, the option of pelletizing the particles into an animal feed pellet (column 6 lines 36-67). However, it makes no mention of any additional or second coating to protect the particle from degradation during the pelletization process.

In summary, the prior art references all teach traditional or conventional rumen by-pass technology, that is, producing a core of physiologically active substance plus binder, the physiologically active substance usually being hygroscopic, and coating the core with a first layer of a hydrophobic substance typically vegetable oil or wax, to protect the core from humidity attack in the rumen so that the core can pass through the rumen without being dissolved/degraded and arrive in the abomasum, where it can be absorbed and utilized by the ruminant. None of these prior art references saw the problem which the present inventors have discovered, that is, that the first layer of coating can be cracked/abraded, degraded, rubbed off, etc. during the pelletization process, thus exposing the core to humidity attack. The present inventors have uniquely discovered the solution to this problem, that is, coating this first layer with a second layer of carnauba wax, which is tough enough and hard enough to protect the first layer from degradation during the harsh pelletization process.

At the conclusion of the interview, the Examiners agreed that claim 1 as now amended may define over the prior art and that further consideration will be given to the application.

Since the present inventors have recognized the problem not recognized previously, that is, the need for a protective second layer to protect the first layer during pelletization, and have also come up with a solution to this problem, that is, providing a second layer mainly consisting of carnauba wax effective to protect the first layer from degradation from abrasion, pressure and mechanical and thermal stress encountered during pelletization of the particles into an animal feed pellet, it is clear that the present invention is an important and dramatic advance over the prior art and is accordingly patentable subject matter. Since the present inventors have come up with an important advance in the field of rumen by-pass, which is not shown or obvious from the prior art, it is clear that claim 1 is now allowable. All the other claims are dependent or otherwise include the limitations of claim 1 and accordingly are allowable by reason of their dependency.

For the foregoing reasons, the claims are now in condition for allowance, which is respectfully requested. If any additional fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-36500.

Respectfully submitted,  
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